

Message

From: Bohnenblust, Eric [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0331C49AEB404367AD226F6BD10D795D-BOHNENBLUST]
Sent: 3/18/2020 6:55:47 PM
To: Milewski, Elizabeth [Milewski.Elizabeth@epa.gov]
Subject: RE: Oxitec response to comment

If there are bolded comments that we can answer I think we should answer them. One thing I can answer is that Oxitec does have a CDC import permit and I have a copy so I can send that. I forwarded him Michelle's response and indicated we hadn't looked at it or touched base with Angela yet but that she is aware.

With regard to the other questions, I haven't quite thought through how to deal with that. If the comments are more nuanced we might need to send some additional comments to OGC but I haven't gone through the summary document with that much of a fine tooth comb yet.

I'm trying to finish our efficacy review this afternoon, so I don't think I can look at it in detail until tomorrow most likely. Might be something to discuss during the team meeting.

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From: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Sent: Wednesday, March 18, 2020 2:48 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Subject: RE: Oxitec response to comment

Hi, Eric. What should we do with this? Particularly his question on whether certain issues that were raised in the last round of comment on OX513A were raised once again for OX5034? The answer to some of these questions is "yes" but some of the nuance is different.

I'm assuming the other issues we specifically asked him to look at we can work through with him as he writes responses to the questions.

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Wednesday, March 18, 2020 1:20 PM
To: Milewski, Elizabeth <Milewski.Elizabeth@epa.gov>
Subject: FW: Oxitec response to comment

Initial thoughts from Ben.

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From: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Sent: Wednesday, March 18, 2020 1:12 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Subject: RE: Oxitec response to comment

Eric,

First, although I am still aiming to get draft responses to you by Sunday (March 22), it might not be until March 31 that I can complete this task. However, it looks like I am probably not going to be on leave next week after all, but even if I am (and haven't yet finished the legal RTCs), then I'll continue working on it next week until it's done. So, I plan to get it done by March 31, regardless of whether I'm on leave next week or not. That said, please let me know ASAP if the "official" target date changes.

As to the legal comments themselves that you sent (attached for reference), here is my present thinking. Please note that I've included **bold, underlined** questions below for BPPD's response:

1) Comments Challenging EPA's Interpretation That FIFRA Can Be Used to Regulate OX5034 Mosquito

Ex. 5 Attorney Client (AC)

2) Comments Arguing the Agency Must Prepare a Full EIS Under the National Environmental Policy Act (NEPA)

Ex. 5 Attorney Client (AC)

However, it looks to me like most of the argument, here, is scientific in nature, as to why "GE mosquitos" are different, or more risky, than other things. As but one example of this:

Ex. 5 Attorney Client (AC)

3) Comments Stating that EPA Must Comply with the Endangered Species Act and Other Laws

Ex. 5 Attorney Client (AC)

4) Veterinary Feed Directive (21 USC 354)

Ex. 5 Attorney Client (AC)

5) Comments Questioning Whether Oxitec Can Be Released from the Contained Use Requirements of an Import Permit

^[1] https://www.cdc.gov/parasites/dirofilariasis/biology_d_immitis.html

^[2] Chihota, C. M., Rennie, L. F., Kitching, R. P., & Mellor, P. S. (2001). Mechanical transmission of lumpy skin disease virus by *Aedes aegypti* (Diptera: Culicidae). *Epidemiology and Infection*, **126**(2), 317–321.

^[3] Fenner, F., Day, M. F., & Woodroffe, G. M. (1952). The mechanism of the transmission of myxomatosis in the European rabbit (*Oryctolagus cuniculus*) by the mosquito *Aedes aegypti*. *The Australian Journal of Experimental Biology and Medical Science*, **30**(2), 139–152.

^[4] Kilham, L., & Dalmat, H. T. (1955). Host-Virus-Mosquito Relations of Shope Fibromas in Cottontail Rabbits. *American Journal of Epidemiology*, **61**(1), 45–54.

^[5] Mweya, C. N., Kimera, S. I., Kija, J. B., & Mboera, L. E. G. (2013). Predicting distribution of *Aedes aegypti* and *Culex pipiens* complex, potential vectors of Rift Valley fever virus in relation to disease epidemics in East Africa. *Infection Ecology & Epidemiology*, **3**(1), 21748.

^[6] Thongyuan, S., & Kittayapong, P. (2017). First evidence of dengue infection in domestic dogs living in different ecological settings in Thailand. *PLOS ONE*, **12**(8), e0180013.

Ex. 5 Attorney Client (AC)

6) EPA Should Not Rely on the Registrant Providing Assessment Data/Information

Ex. 5 Attorney Client (AC)

A) Human studies

Ex. 5 Attorney Client (AC)

B) Oxitec's purposes do not fit appropriate purposes of an EUP

Is there such a comment in play, here?

C) Notification for export of GE insects from the EU per the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Is there such a comment in play, here?

D) New regulations covering GE mosquitos needed in light of FDA's GFI 236

Is there such a comment in play, here?

E) EPA should (must?) do a rulemaking to un-exempt biological control agents

Is there such a comment in play, here?

F) FDA vs. EPA vs. APHIS jurisdiction?

Is there such a comment in play, here?

G) Public hearing required

Is there such a comment in play, here?

H) Migratory Bird Treaty Act and EO 13186

Is there such a comment in play, here?

I) "Legal" arguments regarding "no unreasonable adverse effects" finding under FIFRA

Is there such a comment in play, here?

Please let me know if you'd like to discuss.

Thanks!

- Ben

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From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Wednesday, March 18, 2020 10:29 AM
To: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Subject: RE: Oxitec response to comment

Sounds good, our meeting with Rick is at 430 so anything you can give me before that is helpful. Thanks.

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From: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Sent: Wednesday, March 18, 2020 10:28 AM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Oxitec response to comment

Eric,

I'll be in touch as soon as I can. Other fires burning at the moment.

- Ben

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>
Sent: Wednesday, March 18, 2020 10:25 AM
To: Wakefield, Benjamin J. <wakefield.benjamin@epa.gov>
Cc: Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: Oxitec response to comment

Ben,

I just wanted to check in on your progress. We have a meeting with Rick today to provide an update. As mentioned previously our stated target date in BPPD is mid-April (right now is the 15th), but the existing march 31 date has not been moved at this time.

If you don't think you will finish this week, please let me know. I know you are on leave next week, we will convey what you think is doable to Rick. If you want to discuss on the phone, I have call forwarding on and should be available after 11 am this morning.

Thanks.

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